Co-ordination Group for Mutual Recognition and Decentralised Procedures - Veterinary

EMEA/CMDv/105619/2006

London, 29 March 2006

REPORT FOR RELEASE

Meeting of 16-17 March 2006

Nationally allowed Avian Influenza vaccines, without market authorisation, are not eligible for the Mutual Recognition Procedure. Geographical origin of non-ruminant biological starting materials needs to be stated. Authorisation of diluents not yet harmonised. Two applications referred to CVMP for arbitration.

Avian Influenza vaccines

Following current events Member States may allow the use of vaccines without a marketing authorisation in the absence of a suitable medicinal product and after informing the Commission of the detailed conditions of use[1]. CMD(v) agreed that these products are not eligible for the Mutual Recognition Procedure.

Geographical origin of biological ingredients

At the request of Industry CMD(v) discussed whether the country or geographical region of origin of starting materials of biological origin needs to be stated if the materials are of non-ruminant origin.

According to the legislation[2] the origin and history of biological starting materials shall be described and documented. The European Pharmacopoeia also specifies a number of requirements related to the use of these materials. The risk related to the animal diseases in the country of origin of the substances and to the potential infectious diseases occurring in the source species, in relation to the proposed recipient species, must be carefully evaluated.

The Note for Guidance (NfG) on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (EMEA/410/01 rev 3) states that the source animals and their geographical region is an important element of the risk assessment for minimising the risk. The European Department for the Quality of Medicines (EDQM) Certificates of Compliance will list the source countries of the starting materials derived from TSE-relevant animal species.

For starting materials of biological origin outside the scope of the NfG, it is considered that the European Pharmacopoeia and Directive requirements require the country/geographical region to be provided by the applicant. A CMD(v) position paper on this matter will be published in due course.

[1] Article 8 of Directive 2001/82/EC as amended by Directive 2004/28/EC
[2] Part 6.C.2.1 of the annex of Directive 2001/82/EC

Diluents
The CMD(v) investigated the authorisation practices regarding vaccine diluents in the Member States. Depending on a Member State's position, a diluent is defined as a product, either with or without an active substance, allowing the reconstitution of a lyophilisate / freeze-dried fraction.

There is general agreement that labelling of non-active diluents should be part of a Mutual Recognition or Decentralised Procedure. The Member States have however divergent positions concerning:

- the separate authorisation of diluents;
- the authorisation of diluents for a range of vaccines;
- the labelling of diluents.

Whereas European legislation does not provide clear guidance on these issues and current positions are embedded in national legislation, the need for harmonisation will be brought to the attention of the Heads of Medicines Agencies.

Product discussion
Four applications were discussed at day 78 of the Mutual Recognition Procedure (MRP). One application was discussed for the first time in accordance with the 60 day referral procedure[3].

It was noted that following the February meeting 5 MRP applications were approved. CMD(v) failed however to reach an agreement on two referral procedures within the time given. The main area of disagreement concerned the safety of one product and the efficacy of the other product. The European Medicines Agency was notified, triggering arbitration by the Committee for Medicinal Products for Veterinary Use[4].

Adopted documents
The following documents were finalised/updated:

- Standard Operating Procedure for Veterinary Mutual Recognition Index (VMRI) database;
- Oral explanations, Annex to Standard Operating Procedure for disagreement in procedures, referral to CMD(v);
- Best practice guide (BPG) for repeat use procedure.

Public documents will be made available in due course on the website of the Heads of Agencies www.hevra.org

Information
For questions and further information please contact the CMD(v) secretariat at the European Medicines Agency, for the attention of Wim Riepma, 7 Westferry Circus, Canary Wharf, London, E14 4HB, UK wim.riepma@emea.eu.int

[3] Article 33(1) of Directive 2001/82/EC as amended by Directive 2004/28/EC
[4] Article 33(4) of Directive 2001/82/EC as amended by Directive 2004/28/EC